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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/904,838	07/13/2001	Avi Ashkenazi	10466/72	5331

35489 7590 05/30/2006

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EXAMINER

ROMEO, DAVID S

ART UNIT	PAPER NUMBER
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1647

DATE MAILED: 05/30/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/904,838

Applicant(s)

ASHKENAZI ET AL.

Examiner

David S. Romeo

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 March 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 44-46 and 49-51 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 44-46, 49-51 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: _____

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DETAILED ACTION

Applicants' appeal brief has been considered. However, the arguments are moot in view of the new grounds of rejection. The finality of the last Office action is withdrawn. Claims 44–46 and 49–51 are pending and being examined.

5 **New Formal Matters, Objections And/Or Rejections:**

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

10 (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 44–46 and 49–51 are rejected under 35 U.S.C. 102(e) as being anticipated by

Ebner (U. S. Publication No. 20030069408).

20 This rejection is based upon an effective filing date of 08/21/1997 for Ebner obtained via U.S. Provisional application No. 60/056,565 .

Ebner discloses an isolated human lefty polypeptide having an amino acid sequence that is identical to SEQ ID NO: 114 of the present application, as indicated below:

25 Query Match 100.0%; Score 1928; DB 20; Length 366;
Best Local Similarity 100.0%; Pred. No. 7.4e-183;
Matches 366; Conservative 0; Mismatches 0; Indels 0; Gaps 0;

30 QY 1 MQPLWLCWALWVLPASPGAAITGEQLLGSLLRQLQLKEVPTLDRADMEELVIPTHVRAQ 60
Db 1 MQPLWLCWALWVLPASPGAAITGEQLLGSLLRQLQLKEVPTLDRADMEELVIPTHVRAQ 60

QY 61 YVALLQRSHGDRSRGKRFSQSPREVAGRFLALEASTHLLVFGMEQRLPPNSELVQAVLRL 120
Db 61 YVALLQRSHGDRSRGKRFSQSPREVAGRFLALEASTHLLVFGMEQRLPPNSELVQAVLRL 120

35 QY 121 FQEPVPKAAALHRHGRLSPR SARARVTVEWLRVRDDGSGNRTSLIDSRLVSVHESGWKAPDV 180
Db 121 FQEPVPKAAALHRHGRLSPR SARARVTVEWLRVRDDGSGNRTSLIDSRLVSVHESGWKAPDV 180

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5 QY 181 TEAVNFWQQLSRPRQPLLLQVSVQREHLGPLASGAHKLVRFASQGAPAGLGEPQLELHTL 240
 Db 181 TEAVNFWQQLSRPRQPLLLQVSVQREHLGPLASGAHKLVRFASQGAPAGLGEPQLELHTL 240
 QY 241 DLGDYGAQGDCDPEAPMTEGTRCCRQEMYIDLQGMKWAENWVLEPPGFLAYECVGTCRQP 300
 Db 241 DLGDYGAQGDCDPEAPMTEGTRCCRQEMYIDLQGMKWAENWVLEPPGFLAYECVGTCRQP 300
 10 QY 301 PEALAFKWPFLGPRQCIASETDSLPMIVSIKEGGTRPQVVSLEPNMRVQKSCASDGALV 360
 Db 301 PEALAFKWPFLGPRQCIASETDSLPMIVSIKEGGTRPQVVSLEPNMRVQKSCASDGALV 360
 QY 361 PRRLQP 366
 15 Db 361 PRRLQP 366.

See paragraph [0022].

Ebner also discloses recombinant expression of the Lefty polypeptide in eukaryotic host
 (paragraph [0056]), which would result in cleavage of the signal peptide, and the recombinant
 20 expression of the polypeptide linked to an epitope tag or to the Fc portion of an immunoglobulin
 (paragraph [0090]).

Claim Rejections - 35 USC § 112

Claims 44–46 and 49–51 are rejected under 35 U.S.C. 112, first paragraph, because the
 specification while being enabling for a polypeptide comprising the recited aass, does not
 25 reasonably provide enablement for a polypeptide comprising the recited aass wherein the nucleic
 acid encoding the polypeptide is amplified in lung or colon tumors. The specification does not
 enable a skilled artisan to practice to use the claimed invention.

Due to the degeneracy of the genetic code there are an astronomical number of nucleic
 acid molecules encoding the PRO317 polypeptide. The specification only gives guidance for the
 30 amplification of one such nucleic acid molecule. It is not predictable which, if any, of these
 degenerate nucleic acid molecules occur in nature, and thus would potentially be amplified in
 tumors. The reasonable expectation is that essentially all, except for the naturally occurring
 PRO317 gene, of these nucleic acid molecules would not occur in nature, and thus cannot be
 amplified in lung or colon tumors. In view of the breadth of the claims, the limited amount of

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direction and working examples provided by the inventor, the unpredictability in the art and the quantity of experimentation needed to make or use the invention based on the content of the disclosure, it would require undue experimentation for the skilled artisan to make and/or use the full scope of the claimed invention.

Conclusion

No claims are allowable.

ANY INQUIRY CONCERNING THIS COMMUNICATION OR EARLIER COMMUNICATIONS FROM THE EXAMINER SHOULD BE DIRECTED TO DAVID S. ROMEO WHOSE TELEPHONE NUMBER IS (571) 272-0890. THE EXAMINER CAN NORMALLY BE REACHED ON MONDAY THROUGH FRIDAY FROM 7:30 A.M. TO 4:00 P.M. IF ATTEMPTS TO REACH THE EXAMINER BY TELEPHONE ARE UNSUCCESSFUL, THE EXAMINER'S SUPERVISOR, BRENDA BRUMBACK, CAN BE REACHED ON (571) 272-0961.

IF SUBMITTING OFFICIAL CORRESPONDENCE BY FAX, APPLICANTS ARE ENCOURAGED TO SUBMIT OFFICIAL CORRESPONDENCE TO THE CENTRAL FAX NUMBER FOR OFFICIAL CORRESPONDENCE, WHICH IS (571) 273-8300.

CUSTOMERS ARE ALSO ADVISED TO USE CERTIFICATE OF FACSIMILE PROCEDURES WHEN SUBMITTING A REPLY TO A NON-FINAL OR FINAL OFFICE ACTION BY FACSIMILE (SEE 37 CFR 1.6 AND 1.8).

ANY INQUIRY OF A GENERAL NATURE OR RELATING TO THE STATUS OF THIS APPLICATION OR PROCEEDING SHOULD BE DIRECTED TO THE GROUP RECEPTIONIST WHOSE TELEPHONE NUMBER IS (703) 308-0196.



DAVID ROMEO
PRIMARY EXAMINER
ART UNIT 1647

DSR
MAY 25, 2006